FDA Listing Deficiency Letter – Wonder Pharma -- Action Required

22-OCT-2019

Jane Doe

123 Main Street

Anytown, USA 12345

Dear Jane Doe,

Based on the Food and Drug Administration's (FDA), Drug Registration and Listing Staff quality-control activities, we have found that the strengths in your listed SPL does not match the strengths on the label. The specific National Drug Code(s) (NDC) and associated error(s) or omission(s) that we identified are itemized at the end of this letter.

Under section 510 of the Federal Food, Drug and Cosmetic Act, as amended ("the Act") and Part 207 of FDA's regulations, every person required to register with the FDA must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution, *21 U.S.C. 360(j),(1), see also 21 CFR 207.17 and 207.41.* Drug listing information must be updated in June and December each year. These updates must include any drugs not previously listed, any previously listed drug no longer manufactured or distributed, and certain changes to information for previously listed drugs, *21 U.S.C. 360(j)(2), 21 CFR 207.57.* Failure to properly list a drug product as required by section 510(j) of the Act is prohibited and will render a drug misbranded, *21 U.S.C. 331(p), 352(o).*

Please provide complete and accurate listing information for the drug product(s) included in the table below within 30 days of receipt of this letter and notify us once corrections are made. Non-delivery of the email notification due to outdated contact information will not relieve the firm from its registration and listing obligations. FDA expects firms to provide updated contact information for their establishment registration and labeler code files as required by law. If we do not hear back from you and the corrections are not made within 30 days of the receipt of this letter, further actions will be taken to ensure compliance and accuracy of the data available to public. Depending on the case, such actions may include (but are not limited to) removal from NDC Directory, DailyMed, FDA's Label Repository site and possible warning letters to the firm.

In order to make correction(s), the existing listing file(s) for the drug(s) below should be accessed and revised. Any new listing information or updates to existing listing files should be submitted via Structured Product Labeling (SPL) using the electronic registration and listing system. For information on how to use the system visit: http://www.fda.gov/eDRLS. If submission of the revised SPL(s) results in a validation error, an override request should be sent to the SPL Coordinator at spl@fda.hhs.gov with a copy of this letter for a manual override. If you believe you have received this notification in error or if you have further questions contact eDRLS@fda.hhs.gov.

Please note that listing a product with the FDA does not mean that the FDA has made a finding that your product is a legally marketed drug. This is not an all-inclusive letter containing all listing errors associated with your products. It remains your responsibility to determine whether your firm and its products are in compliance with applicable laws.

Sincerely,

Electronic Drug Registration and Listing Staff (jac)

FDA/CDER/Office of Compliance

edrls@fda.hhs.gov

NDC	Proprietary/ Non-Proprietary Name	Error
55555-555-01	Wonderdrug 2% ointment	Incorrect strength